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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/782,695	02/19/2004	Maria A. Glucksmann	MPI04-002OMNIM	4730

30405 7590 03/22/2007
MILLENNIUM PHARMACEUTICALS, INC.
40 Landsdowne Street
CAMBRIDGE, MA 02139

EXAMINER

JIANG, DONG

ART UNIT	PAPER NUMBER
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1646

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	03/22/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/782,695

Applicant(s)

GLUCKSMANN ET AL.

Examiner

Dong Jiang

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 December 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 19-28 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 19-28 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>7/24/06</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED OFFICE ACTION

Applicant's election with traverse of Group I invention filed on 22 December 2006 is acknowledged. However, because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Applicant's amendment filed on 22 December 2006 is acknowledged and entered. Following the amendment, claims 23 and 28 are amended.

Currently, claims 19-28 are pending and under consideration.

Formal Matters:

Information Disclosure Statement

Applicant's IDS submitted on 7/24/06 is acknowledged and has been considered. A signed copy is attached hereto. Note, since the sequence search result cited on the information disclosure statement (document# U) is not true publications with a publication date, it is not fully in compliance with 37 CFR 1.97, and thus it will not be printed on the face of the patent issuing from this application.

Priority acknowledgement

This application claims priority to more than 14 US applications and US provisional applications. Upon reviewing these applications, the examiner determined that the present claims 19-28 are only entitled to the benefit of the filing date of prior applications 09/945, 254 filed on 8/31/01, and 60/229,829 filed on 8/31/00, in which the sequences of SEQ ID NO:13-15 were disclosed for the first time. None of the other claimed prior applications discloses the sequences of SEQ ID NO:13-15, which are the subject matter of the instant invention.

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Specification***Title***

The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the elected claims are directed.

The use of the trademarks TaqmanTM, TaqManTM and AmpliTaqTM (pages 257 and 258, for example) have been noted in this application. It should be capitalized wherever it appears and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

Rejections under 35 U.S.C. §101 and §112:

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 19-28 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility.

Claims 19-28 are directed to a method for identifying a compound capable for *treating* lung, breast and colon cancer, wherein the compound supposedly binds to the polypeptide of SEQ ID NO:14, and inhibit growth or proliferation of the cancer cells. The specification discloses that the polypeptide of SEQ ID NO:14 is a novel human galactosyltransferase member based as it possesses a galactosyltransferase family domain (page 254, [0880]), and is designated "HGT-1". The specification further teaches the expression profile of said HGT-1 (Taqman analysis, a quantitative, real-time PCR-based approach), which is highly expressed in some normal tissues, cells and cell lines, and in some colon, lung and breast tumors (page 258, [0893], and page 259, [0895]-[0897]), and teaches that expression of HGT-1 is induced upon treatment of MCF10A cells with the growth factors RGF or IGF1A, and is strongly induced in MCF10A

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cells grown in agar, indicating that HGT-1 expression is increased upon progression from a pre-malignant to a malignant state (page 258, [0898]). However, the specification does not disclose how the increase in HGT-1 expression in the tumor cells is related to the cell transformation, i.e., whether the increase in HGT-1 expression in the tumor cells is responsible in any way for tumor formation or progression. Therefore, it is unclear whether the increase in HGT-1 expression in the tumor cells is the cause or just a concurrent event during the cell transformation or progression from a pre-malignant to a malignant state. Thus, the specification fails to establish a causal relationship between said HGT-1 and tumor formation or progression, which is the most important element with respect to determining targeting HGT-1 for the cancer treatment, because the expression of many molecules can be altered (increased, for example) in tumor cells, and they are not necessarily responsible for cell transformation or tumor progression.

Clearly the utility of the polypeptide of SEQ ID NO:14 associated with cancer treatment requires additional knowledge about the polypeptide before the polypeptide can be used for the specific purpose (as a target for cancer treatment, or for identifying a compound for treating cancer), and further research/experimentation is required in order to determine whether the polypeptide of SEQ ID NO:14 in the cancer cells are responsible for the tumor formation and/or progression, and therefore, it can be used as a target for therapy. As such, the claimed method is not supported by a substantial utility because, according to MPEP, a **substantial utility** is a utility that defines “real world” use, and a utility that requires or constitutes carrying out further research to identify or reasonably confirm a “real world” context of use is not a substantial utility. In *Brenner v. Manson*, 148 U.S.P.Q. 689 (Sus. Ct, 1966), the court held that:

The basic quid pro quo contemplated by the Constitution and the Congress for granting a patent monopoly is the benefit derived by the public from an invention with substantial utility. . . . [u]nless and until a process is refined and developed to this point-where specific benefit exists in currently available form-there is insufficient justification for permitting an applicant to engross what may prove to be a broad field. . . . a patent is not a hunting license. . . . [i]t is not a reward for the search, but compensation for its successful conclusion.

In the instant case, without knowing whether the polypeptide of SEQ ID NO:14 is responsible for the tumor progression, the use of the polypeptide for identifying a compound capable of treating the cancer is not substantial, and therefore, the claimed method is not in currently available form (i.e., for “real world” use) as of the filing date, which is required by the utility standard under 35 U.S.C. §101. The current findings that mRNA encoding the

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polypeptide of SEQ ID NO:14 is elevated in said tumor cells is tantalizing, which, at the most, is an interesting invitation for further research and experimentation in order to define a *"real world"* use for the polypeptide with this regard, such as that of the instant invention. Upon further research, a substantial utility might be found for the claimed method. This further characterization, however, is part of the act of invention, and until it has been undertaken, the claimed invention is incomplete, and cannot be considered substantial.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 19-28 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

Prior Art:

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Conklin et al. (WO 01/44479, 21 June 2001, provided by applicants) discloses a human galactosyltransferase homolog, ZNSSP8, which amino acid sequence of SEQ ID NO:2 is 100% identical to the present SEQ ID NO: 14.

Baughn et al. (US 2003/0143589 A1) discloses a human drug metabolizing enzyme, DME-10, which amino acid sequence of SEQ ID NO:10 is 100% identical to the present SEQ ID NO: 14.

Conclusion:

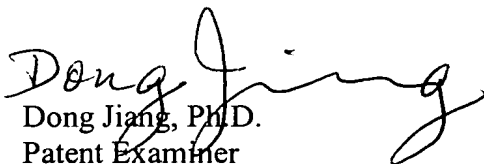
No claim is allowed.

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Advisory Information:

Any inquiry concerning this communication should be directed to Dong Jiang whose telephone number is 571-272-0872. The examiner can normally be reached on Monday - Friday from 9:30 AM to 7:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Nickol, can be reached on 571-272-0835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

A handwritten signature in cursive script, appearing to read "Dong Jiang".

Dong Jiang, Ph.D.
Patent Examiner

AU1646

3/8/07